



1006 Rec'd PTO 17 OCT 2005

10/524263

Docket No.: H6808.0075/P075
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Takayuki Kanda et al.

Application No.: 10/524,263

Confirmation No.: 4131

Filed: February 11, 2005

Art Unit: 1646

For: METHOD OF AMPLIFYING NUCLEIC
ACID AND APPARATUS THEREFOR

Examiner: Not Yet Assigned

**RESPONSE TO NOTICE TO COMPLY WITH REQUIREMENTS
FOR PATENT APPLICATION CONTAINING NUCLEOTIDE
SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

MS Sequence
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures, dated August 16, 2005. Applicants are submitting their response herewith within the two-month response period set to expire on October 16, 2005.

The U.S. Patent and Trademark Office has taken the position that the previous "Sequence Listing" in computer readable form did not comply with the requirements of Section 1.824 for the stated reason that it contained several raw sequence listing errors. Submitted herewith in connection with the above-referenced patent application is a substitute, computer readable copy of the Sequence Listing that

corrects the defects noted in the raw sequence listing. No new matter has been added to the substitute Sequence Listing.

Applicants respectfully request the above-referenced patent application be placed upon the files for examination.

Dated: October 17, 2005

Respectfully submitted,

By 

Mark J. Thronson

Registration No.: 33,082

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Registration No.: 40,399

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

U.S. APPLICATION NUMBER NO. 10/524,263	FIRST NAMED APPLICANT Takayuki Kanda	ATTY. DOCKET NO. H6808.0075/P075
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INTERNATIONAL APPLICATION NO.

PCT/JP02/11815

IA. FILING DATE	PRIORITY DATE
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11/13/2002

24998

DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP
 2101 L Street, NW
 Washington, DC 20037

MC 18 2005
 MJT
 LMS 8-18-05 MC 8-19-05

CONFIRMATION NO. 4131
 371 FORMALITIES LETTER
 OC000000016784410
 OC000000016784410

Date Mailed: 08/16/2005

NOTIFICATION TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant is given **TWO MONTHS FROM THE DATE OF THIS NOTICE** within which to file the items indicated below to avoid abandonment. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing." Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d).

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

WINSTON M ALVARADO

Telephone: (703) 308-9140 EXT 206

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/524,263	PCT/JP02/11815	H6808.0075/P075

FORM PCT/DO/EO/922 (371 Formalities Notice)

10/524263

STIC Biotechnology Systems Branch

RAW SEQUENCE LISTING
ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 10/524,263
Source: PG/10
Date Processed by STIC: 2/23/05

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.

PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT MARK SPENCER, TELEPHONE: 571-272-2510; FAX: 571-273-0221

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 4.2.2 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

<http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm>

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.

Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.

Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<<http://www.uspto.gov/ebc/efs/downloads/documents.htm>> , EFS Submission User Manual - ePAVE)
2. U.S. Postal Service: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
3. Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 01/14/05):
U.S. Patent and Trademark Office, Mail Stop Sequence, Customer Window, Randolph Building, 401 Dulany Street, Alexandria, VA 22314

Revised 01/24/05

*Please send this error report
with the notice.*

William Alvarado
National Stage Processing
Patent Specialist
(703) 305-6421

Raw Sequence Listing Error Summary

ERROR DETECTED

SUGGESTED CORRECTION

SERIAL NUMBER: 10/524,263

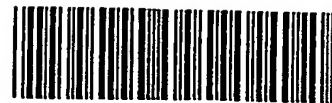
ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

- 1 ☐ Wrapped Nucleics
Wrapped Aminos The number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to .3; this will prevent "wrapping."
- 2 ☐ Invalid Line Length The rules require that a line not exceed 72 characters in length. This includes white spaces.
- 3 ☐ Misaligned Amino
Numbering The numbering under each 5th amino acid is misaligned. Do not use tab codes between numbers; use space characters, instead.
- 4 ☒ Non-ASCII The submitted file was not saved in ASCII(DOS) text, as required by the Sequence Rules. Please ensure your subsequent submission is saved in ASCII text.
- 5 ☐ Variable Length Sequence(s) contain n's or Xaa's representing more than one residue. Per Sequence Rules, each n or Xaa can only represent a single residue. Please present the maximum number of each residue having variable length and indicate in the <220>-<223> section that some may be missing.
- 6 ☐ PatentIn 2.0
"bug" A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequences(s). Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies to the mandatory <220>-<223> sections for Artificial or Unknown sequences.
- 7 ☐ Skipped Sequences
(OLD RULES) Sequence(s) missing. If intentional, please insert the following lines for each skipped sequence:
(2) INFORMATION FOR SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)
(i) SEQUENCE CHARACTERISTICS: (Do not insert any subheadings under this heading)
(xi) SEQUENCE DESCRIPTION: SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)
This sequence is intentionally skipped

Please also adjust the "(ii) NUMBER OF SEQUENCES:" response to include the skipped sequences.
- 8 ☐ Skipped Sequences
(NEW RULES) Sequence(s) missing. If intentional, please insert the following lines for each skipped sequence.
<210> sequence id number
<400> sequence id number
000
- 9 ☐ Use of n's or Xaa's
(NEW RULES) Use of n's and/or Xaa's have been detected in the Sequence Listing.
Per 1.823 of Sequence Rules, use of <220>-<223> is MANDATORY if n's or Xaa's are present.
In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.
- 10 ☐ Invalid <213>
Response Per 1.823 of Sequence Rules, the only valid <213> responses are: Unknown, Artificial Sequence, or scientific name (Genus/species). <220>-<223> section is required when <213> response is Unknown or is Artificial Sequence
- 11 ☐ Use of <220> Sequence(s) missing the <220> "Feature" and associated numeric identifiers and responses.
Use of <220> to <223> is MANDATORY if <213> "Organism" response is "Artificial Sequence" or "Unknown." Please explain source of genetic material in <220> to <223> section.
(See "Federal Register," 06/01/1998, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of Sequence Rules)
- 12 ☐ PatentIn 2.0
"bug" Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other manual means to copy file to floppy disk.
- 13 ☐ Misuse of n/Xaa "n" can only represent a single nucleotide; "Xaa" can only represent a single amino acid

AMC - Biotechnology Systems Branch - 09/09/2003

Best Available Copy



P0

see item 4 on Error Summary sheet

RAW SEQUENCE LISTING

PATENT APPLICATION: US/10/524,263

DATE: 02/23/2005

TIME: 09:14:13

Input Set : A:\PTO.SR.txt

Output Set: N:\CRF4\02232005\J524263.raw

3 <110> APPLICANT: HITACHI HIGH-TECHNOLOGIES CORPORATION
 5 <120> TITLE OF INVENTION: METHOD AND APPARATUS FOR DETECTING NUCLEIC ACID
 7 <130> FILE REFERENCE: PH-1502-PCT
 9 <140> CURRENT APPLICATION NUMBER: US/10/524,263
 10 <141> CURRENT FILING DATE: 2005-02-11
 12 <160> NUMBER OF SEQ ID NOS: 3
 14 <170> SOFTWARE: PatentIn Ver. 2.1

ERRORED SEQUENCES

34 <210> SEQ ID NO: 3
 35 <211> LENGTH: 50
 36 <212> TYPE: DNA
 37 <213> ORGANISM: Artificial Sequence
 W--> 39 <220> FEATURE:
 W--> 39 <223> OTHER INFORMATION:
 W--> 39 <400> 3
 C--> 40 tctagcctca atcctcatac
 E--> 46 1/2
 E--> 47 dsmdb.1883558.1

pp 1-2
Does Not Comply
Corrected Diskette Needed

*use lower-case
 letters for nucleotides*

delete

see p. 2 for error explanation

20

*(same
 error in
 sequence 10)*

RAW SEQUENCE LISTING ERROR SUMMARY
PATENT APPLICATION: US/10/524,263

DATE: 02/23/2005
TIME: 09:14:14

Input Set : A:\PTO.SR.txt
Output Set: N:\CRF4\02232005\J524263.raw

error explanation

Use of <220> Feature(NEW RULES):

Sequence(s) are missing the <220> Feature and associated headings.

Use of <220> to <223> is MANDATORY if <213> ORGANISM is "Artificial Sequence" or "Unknown". Please explain source of genetic material in <220> to <223> section (See "Federal Register," 6/01/98, Vol. 63, No. 104, pp.29631-32) (Sec.1.823 of new Rules)

Seq#:1,2,3

VERIFICATION SUMMARY

PATENT APPLICATION: US/10/524,263

DATE: 02/23/2005

TIME: 09:14:14

Input Set : A:\PTO.SR.txt

Output Set: N:\CRF4\02232005\J524263.raw

L:9 M:270 C: Current Application Number differs, Replaced Application Number
L:10 M:271 C: Current Filing Date differs, Replaced Current Filing Date
L:21 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:1, <213>
ORGANISM:Artificial Sequence
L:21 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:1, <213>
ORGANISM:Artificial Sequence
L:21 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:1,Line#:21
L:22 M:112 C: (48) String data converted to lower case,
L:30 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:2, <213>
ORGANISM:Artificial Sequence
L:30 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:2, <213>
ORGANISM:Artificial Sequence
L:30 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:2,Line#:30
L:31 M:112 C: (48) String data converted to lower case,
L:39 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ#:3, <213>
ORGANISM:Artificial Sequence
L:39 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ#:3, <213>
ORGANISM:Artificial Sequence
L:39 M:258 W: Mandatory Feature missing, <223> Blank for SEQ#:3,Line#:39
L:40 M:112 C: (48) String data converted to lower case,
L:46 M:254 E: No. of Bases conflict, LENGTH:Input:2 Counted:21 SEQ:3
L:46 M:320 E: (1) Wrong Nucleic Acid Designator, NUMBER OF INVALID KEYS:2
M:254 Repeated in SeqNo=3
L:47 M:320 E: (1) Wrong Nucleic Acid Designator, NUMBER OF INVALID KEYS:9
M:112 Repeated in SeqNo=3
L:47 M:252 E: No. of Seq. differs, <211> LENGTH:Input:50 Found:28 SEQ:3